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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,600	02/11/2002	Jinglin Li	161765.00465 (SO-3163/01/	2753

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EXAMINER
SACKEY, EBENEZER O

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/072,600	JINGLIN LI ET AL.
Examiner	**Art Unit**
EBENEZER SACKEY	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 6, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 65, and 66* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 65, and 66* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Mar 6, 2002* is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim 1 and new claims 65 and 66 are pending.

Receipt of the Preliminary amendment and Information Disclosure Statement filed on 06/06/02 is acknowledged and has been entered into the file. Claims 2-64 have been canceled.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point

out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 65-66 (in part) are, drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide of formula (I) wherein R^1 and R^2 is H, alkyl, alkenyl and alkynyl; R^3 is H, alkyl, alkenyl, alkynyl, aryl and cycloalkyl where aryl can be substituted with alkyl, alkenyl, alkynyl, polyalkyl and OR^{19} wherein R^{19} is H, alkyl, alkenyl, alkynyl, polyalkyl; R^4, R^5, R^6, and R^7 are H, alkyl, alkenyl, alkynyl and halo, classified in class 549, subclass 9.

II. Claims 1 and 65-66 (in part) are, drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide of formula (I) wherein R^1, R^2 and R^3 are heteroaryl and quaternary heteroaryl, R^4-R^7 is heteroaryl classified in class 549, in various subclasses.

III. Claims 1 and 65-66 (in part) are, drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine of formula (I) wherein R^1, R^2 and R^3 is heterocycle or quaternary heterocycle, R^4-R^7 is hydrogen, alkyl, alkenyl, alkynyl, classified in class 549, in various subclasses.

IV. Claims 1 and 65-66 (in part), drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine of formula (I) wherein R^1, R^2 and R^3 is SR^{15}, $S(O)R^{15}$, SO_2R^{15}, SO_3R^{15}, R^4-R^7 is alkyl, alkenyl, alkynyl, classified in class 549 in various subclasses.

V. Claims 1 and 65-66 (in part) are, drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide of

formula (I) wherein R^1, R^2 and R^3 is OR^{19}, $N^{19}R^{20}$, SR^{19}, $S(O)R^{19}$, SO_2R^{19}, SO_3R^{19}, $NR^{19}R^{20}$, $NR^{19}NR^{20}R^{21}$, NO_2 , CO_2R^{19}, CN, OM, SO_2OM, $SO_2NR^{19}R^{20}$, $C(O)NR^{19}R^{20}$, C(O)OM, COR^{19}, $S^+R^{19}R^{20}A^-$, $N^+R^{15}R^{17}R^{18}A^-$, R^4-R^7 is NO_2, NR^9R^{10}, classified in class 549, in various subclasses.

VI. Claims 1 and 65-66 (in part) are, drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine of formula (I) wherein R^1, R^2 and R^3 is $P(O)R^{19}R^{20}$, $P^+R^{19}R^{20}R^{21}A^-$, $P(OR^{19})OR^{20}$, $S^+R^{19}R^{20}A^-$, $N^+R^{15}R^{17}R^{18}A^-$, R^4-R^7 is hydrogen, alkyl classified in class 549, in various subclasses.

VII. Claims 1 and 65-66 (in part), drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine of formula (I) wherein R^1, R^2 and R^3 is guanidinyl, ammoniumalkyl, alkylammoniumalkyl, R^4-R^7 is hydrogen, alkyl, classified in class 549 in various subclasses.

2. The above Groups are listed as general areas and are not exhaustive. Each group is independent or distinct and are capable of preparation by

more than one process (as note the instant specification). Separate search considerations are involved. Moreover, not to restrict, the claims would impose a substantial burden on the examination of the application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, a method of preparing an enantiomerically-enriched derivatives of tetrahydrobenzothiepine-1-oxide of formula (I) are generic with the provisionally elected Group.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the

evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Ajay Pathak on 01/10/03 a provisional election was made with traverse to prosecute the invention of Group I, example 7, (preparation of the enantiomerically-enriched tetrahydrobenzothiepine-1-oxide((4R,5R)-XXIV), page 46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 and 65-66 (in part), other than wherein R^1 and R^2 is all substituents except heteroaryl and R^3, R^4-R^7 is hydrogen, hydrocarbons and OR^{24} are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 and 65-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (U.S.Patent No 5,994,391).

Applicants claim a method of preparing an enantiomerically-enriched tetrahydrobenzotiepine-1-oxide of formula (I), wherein the method comprises cyclizing an enantiomerically-enriched aryl-3-propanesulfoxide of formula (II) in the presence of a base (potassium t-butoxide) to obtain the enantiomerically-enriched compound of formula (I). The reference, '391'

discloses a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide compound, wherein the method comprises cyclizing an enantiomerically-enriched aryl-3-propanesulfoxide compound in the presence of a base (potassium t-butoxide in THF) to obtain the enantiomerically-enriched compound of formula (I). See for example, step 7, column 296, lines 40-60.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1 and 65-66 are rejected under 35 U.S.C. 103(a) as being obvious over Lee et al. (U.S.Patent No 5,994,391).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection

under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See M.P.E.P.. § 706.02(l)(1) and § 706.02(l)(2).

Applicants claim a method of preparing an enantiomerically-enriched tetrahydrobenzotiepine-1-oxide of formula (I), wherein the method comprises cyclizing an enantiomerically-enriched aryl-3-propanesulfoxide of formula (II) in the presence of a base (potassium t-butoxide) to obtain the enantiomerically-enriched compound of formula (I).

The reference, '391' discloses several methods of preparing an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide compound. One of the methods comprises cyclizing an enantiomerically-enriched aryl-3-propanesulfoxide compound in the presence of a base (potassium t-butoxide in THF) to obtain the enantiomerically-enriched compound of formula (I). See for example, step 7, column 296, lines 40-60. Another method method involves several reactive steps whereby different intermediates are produced, see column 259, lines 1-67. The instant method differs from Lee et al. in that the instant method requires a two-step process for preparing formula (I), whereas the reference discloses several alternative methods of producing formula (I) including the two-step process.

Since the prior art teaches cyclizing methods similar to the instantly claimed methods, one of ordinary skill in the art would be motivated to prepare compounds as claimed with some expectation of improving the yield and selectivity. The claimed methods would be obvious from the reference's disclosure absent a showing of any unobvious or unexpected properties especially since one of ordinary skill would expect that methods so closely related would produce similar compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

February 24, 2003

Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1626, Group 1600

Technology Center 1